

**CHANGES IN SCANNING OF RESEARCH PARTICIPANT DOCUMENTS:**

- **Signed research informed consent documents and HIPAA authorizations *should no longer be delivered to the R&D Service for scanning purposes.***
- **However, you must *continue to deliver acknowledgements of Notices of Privacy practices (NOPP) (VAF 10-0483) to the R&D Service.***

■ **Informed Consent & HIPAA Authorization Forms.** There is no longer a requirement to scan informed consent and HIPAA documents into CPRS. As of May 31, 2015, the R&D Service has stopped scanning these forms into CPRS.

- There ***is*** still a need for the Office of Research Compliance (ORC) to have access to these forms for its mandated annual audits of consent documents. A Bulletin or Hot Topic will be issued when there is a new process in place for ORC audits.
- ***Effective immediately, stop bringing ICFs and HIPAAs to the R&DS Office.*** Instead, keep the copies in your study area until needed by the ORC, or hold off on making copies until the new ORC process is settled.
- Any informed consent documents delivered to the R&DS since the end of scanning have been saved in the RDS Office and will be made available to the ORC. Therefore you will NOT need to re-copy/re-send any packets already sent to the R&DS.

■ **There is no longer a VA requirement to enter consent/enrollment notes into CPRS.** However:

- **Enrollment notes must still be placed in the study's research files.**
- **Locally, CPRS progress notes are required throughout the study for any intervention, assessment, or concern that would affect the medical care or health of the participant.** This is consistent with the practice for VAMHCS clinical progress notes. The progress note might also state the participant's enrollment into the research study, and give contact information for the study team if that information affects the medical care or health of the participant.

*A progress note must be created in CPRS for all research subjects (Veterans or Non-Veterans) who are admitted to VA medical facilities as in-patients, treated as outpatients at VA medical facilities, or when research procedures or interventions are used in or may impact the medical care of the research subject at a VA medical facility or at facilities contracted by VA to provide services to Veterans. [VHA HB 1200.05§29.]*

- **NOPP acknowledgements (VAF 10-0483)**. There is still a requirement for the R&DS to scan NOPP acknowledgements (VAF 10-0483) of non-Veterans into CPRS. See [R&D Service Hot Topic Vol.5 No.1a](#) for information about acknowledgements of the VA Notice of Privacy Practices.
  - **Use the new [Cover Sheet for Signed 10-0483's \(or equivalent\)](#) to continue sending 10-0483's to the R&DS.** The new cover sheet is attached and is also available on the R&D Service website.
  - Remember that the 10-0483 requirement applies only to **non-Veteran** research participants who **have CPRS charts**.
  - If a 10-0483 has already been obtained and scanned for the participant, there is no need to obtain additional 10-0483's. Unfortunately it is not easy to find 10-0483's in CPRS. You can do any of the possibilities below:
    - Obtain a 10-0483 from the participant just to be sure.
    - Look in past research enrollment notes and look through the scanned documents attached to the notes to see if a 10-0483 has been scanned.
    - Contact Jessica Mendoza to see if it is on the R&DS NOPP log.
  - Please be sure that the 10-0483 is completely filled out: signature, date, and last 4 digits of the SSN.
  - **Instructions for the [cover sheet](#):**
    - Column 2: Fill out the participant's **entire last name** and last 4 digits of the SSN. This is because the signature or name printed on the 10-0483 is often illegible.
    - Column 3: Confirm that the participants listed on the cover sheet ARE non-Veterans.
    - Column 4: Confirm that a CPRS chart DOES exist for the participant.
    - Column 5: Confirm that a 10-0483 is attached.

- Column 6: If a participant is a non-Veteran and does have a CPRS chart but no 10-0483 is attached, then state the reason why. Possible reasons might be: “forgot to obtain, will get at next visit”, “forgot to obtain but it is not possible to obtain in the future”, “has already been scanned for this individual (include date of enrollment note if possible)”, or whatever other reason applies.
- **Equivalent to cover sheet.** If your study master list or other study documentation contains the same information as the [Cover Sheet for Signed 10-0483](#)’s, then you may use that list (or excerpt of the list) instead of the Cover Sheet. This is to decrease duplication of effort for the study team.
- Send the 10-0483 packets to the R&DS in intervals practical for your study. For example, send the packets on a monthly basis, or a quarterly basis, or when “x” number of 10-0483’s have been collected, etc.
- Deliver the packets into the “treasure box” in the R&DS mailroom in 3D-160.

For questions concerning this or other Research Service Hot Topics OR for adding staff or colleagues to the Hot Topics mailing list, contact:

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Can’t put your finger on a past Hot Topic you know would solve your problem? No problem. Check the Hot Topics archive on the Research Service website:  
[http://www.maryland.research.va.gov/hot\\_topics.asp](http://www.maryland.research.va.gov/hot_topics.asp)